



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0530]

Guidance for Industry: Considering Whether a Food and Drug Administration-Regulated Product Involves the Application of Nanotechnology; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance entitled "Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology." This guidance explains FDA's current thinking on determining whether FDA-regulated products involve the application of nanotechnology. The guidance identifies two Points to Consider, which address both particle dimensions and dimension-dependent properties or phenomena. If either point applies to a given product, industry and FDA should consider whether evaluations of safety, effectiveness, public health impact, or regulatory status of that product have identified and adequately addressed any unique properties or behaviors of the product. These two Points to Consider are intended to provide an initial screening tool that can be broadly applied to all FDA-regulated products, with the understanding that these points are subject to change in the future as new information becomes available.

DATES: Submit either electronic or written comments on FDA guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance entitled "Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of

Nanotechnology" to the Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ritu Nalubola, Office of Policy, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4236, Silver Spring, MD 20993-0002, 301-796-4830, email: [Ritu.Nalubola@fda.hhs.gov](mailto:Ritu.Nalubola@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

## I. Background

We are announcing the availability of a guidance entitled "Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology."

This guidance is intended for manufacturers, suppliers, importers, and other stakeholders. It describes FDA's current thinking on determining whether FDA-regulated products involve the application of nanotechnology. In the Federal Register of June 14, 2011 (76 FR 34715), we made available a draft guidance entitled "Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology" and gave interested parties an opportunity to submit comments by August 15, 2011, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance and have modified the final guidance, where appropriate. The guidance announced in this notice finalizes the draft guidance dated June 2011.

This guidance provides an overarching framework for FDA's approach to the regulation of nanotechnology products. Based on our current scientific and technical understanding of nanomaterials and their characteristics, FDA believes that evaluations of safety, effectiveness, public health impact, or regulatory status of nanotechnology products should consider any unique properties and behaviors that the application of nanotechnology may impart. This guidance identifies two Points to Consider that should be applied when considering whether FDA-regulated products involve the application of nanotechnology. These Points address both particle dimensions and dimension-dependent properties or phenomena. If either point applies to a given product, industry and FDA should consider whether the evaluations of safety, effectiveness, public health impact, or regulatory status of that product have identified and adequately addressed any unique properties or behaviors of the product.

These two Points to Consider are intended to provide an initial screening tool that can be broadly applied to all FDA-regulated products, with the understanding that these points are subject to change in the future as new information becomes available. In particular, FDA may further refine these points, either as applicable broadly to all FDA-regulated products or as applicable to particular products or classes of products, as justified by scientific information.

We will consider future revisions to our approach, including developing regulatory definitions relevant to nanotechnology, as warranted and in keeping with evolving scientific understanding. FDA may also provide additional guidance, including product-specific guidance documents, to address issues such as the regulatory status, safety, effectiveness, performance, quality, or public health impact of nanotechnology products.

We urge industry to consult early with FDA so that any questions related to the regulatory status, safety, effectiveness, or public health impact of products that involve the application of nanotechnology can be appropriately and adequately addressed.

## II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if such approach satisfies the requirements of applicable statutes and regulations.

## III. Comments

Interested persons may submit either electronic comments regarding the guidance to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: June 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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